

REMARKS

Upon entry of the above amendment, claims 20-25 will be pending in this application. Claims 1-19 have been canceled without prejudice or disclaimer. Applicant, by canceling any claims herein, makes no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicant reserves the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Basis for the new claims may be found throughout the present specification. In particular, basis for new independent claim 20 may be found in originally filed claim 10, as well as Examples 1, 2, 5, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 20, 21, 26, 27, 28, 29, 30, 31, 32, 34 and 35.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At pages 3-6 of the Official Action, claims 1-12 and 14 have been rejected under 35 U.S.C. § 112, first paragraph for lack of enablement.

The Examiner asserts at page 3 that the specification "does not reasonably provide enablement for ... all the various groups as claimed". Applicant respectfully traverses this rejection.

The enablement provision of the Patent Act requires that the patentee provide a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same." 35 USC § 112, first paragraph (2000). The purpose of this requirement is to ensure that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims."

Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195-96 (Fed. Cir. 1999); see also Donald S. Chisum, 3 *Chisum on Patents* § 7.01 (2002).

Accordingly, the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). "The key word is 'undue,' not 'experimentation.'" *Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Routine experimentation does not constitute undue experimentation. See *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. See, e.g., *Nat'l Recovery Techs.*, 166 F.3d at 1196 ("The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation."); *Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." See *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993).

Although the ultimate determination of whether one skilled in the art could make and use the claimed invention without undue experimentation is a legal one, it is based on underlying findings of fact. *CFMT*, 349 F.3d at 1337. Furthermore, “[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *Wands*, 858 F.2d at 737.

Some of these considerations, commonly referred to as “the *Wands* factors,” include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.*; see also *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991) (stating that the *Wands* factors “are illustrative, not mandatory” and that what is relevant to an enablement determination depends upon the facts of the particular case).

In the present case, Applicant respectfully submits that the specification provides ample guidance to the skilled artisan in view of the state of the art at the time the application was filed, to make and use the presently claimed subject matter without undue experimentation.

Applicant further points out to the Examiner that each of the rejected claims has been canceled without prejudice or disclaimer, rendering the basis of this rejection moot to these now canceled claims. However, applicant has introduced new independent claim 20 and new dependent claims 21-25 which depend either directly or indirectly from new claim 20 – all of which are indeed enabled by the instant specification. In this

regard, applicant specifically points to Examples 1, 2, 5, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 20, 21, 26, 27, 28, 29, 30, 31, 32, 34 and 35 in the instant specification.

In view of the direct disclosure contained in the instant specification regarding the twenty-five Example compounds, as well as the disclosure contained on pages 39-52 regarding various Reaction Schemes, it is quite clear that a person of ordinary skill would not have to undertake undue experimentation to arrive at the presently claimed subject matter.

As such, applicant respectfully submits that presently pending claims 20-25 comply with the enablement requirements of 35 USC § 112, first paragraph. Accordingly, applicant respectfully requests that the Examiner reconsider her position in view of the presently pending claims and allow the presently pending claims to proceed to grant.

II. At pages 6-14 of the Official Action, claims 1-12 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 99/05113, WO 00/42020, WO 00/42017, WO 97/28131, WO 2004/018431, WO 02/06238, WO 2004/019945, WO 2005/077906, WO 02/05616 and WO 99/05111.

Applicant respectfully traverses this rejection and respectfully points out to the Examiner that each of the rejected claims has been canceled without prejudice or disclaimer, rendering the basis of this rejection moot to these now canceled claims. However, applicant has introduced new independent claim 20 and new claims 21-25 which depend either directly or indirectly from new claim 20 – all of which are not obvious over the disclosure contained in the ten cited documents.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 167 L.Ed. 705 (2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR, supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Further, the Supreme Court in *KSR* reiterated the framework for determining obviousness that was stated in *Graham v. John Deere Co.* 383 U.S. 1, 148 USPQ 459 (1966). The four factual inquiries that were recited in *Graham* are as follows: (1)

Determining the scope and contents of the prior art; (2) Ascertaining the differences between the prior art and the claims in issue; (3) Resolving the level of ordinary skill in the pertinent art; and (4) Evaluating evidence of secondary considerations, such as unexpected results. *Id.* As stated in **MPEP 2141**, secondary considerations such as unexpected results must be considered in every case in which they are present.

The cited references do not teach each and every element of the presently claimed subject matter. Specifically, the WO 99/05113 reference does not teach the possibility of R4/R5 being hydroxyl (i.e. a 2-hydroxy substituent) and further allows the 6-phenyl moiety to be substituted with either -SO₂-N(R7)R8 or -CO-N(R9)R10 wherein R9 = H or alkyl and R10 = an optionally substituted pyridyl or phenyl radical. Accordingly, the cited WO 99/05113 reference does not teach the presently claimed substituents.

Further, the WO 00/42020 reference does not teach the possibility of a 2-hydroxy substituent and allows the 6-phenyl substituent to be, among other things, -C(O)-4-methyl-piperazin-1-yl or -C(O)-4-morpholinyl. Accordingly, the cited WO 00/42020 reference does not teach the presently claimed substituents.

Further, the WO 00/42017 reference does not teach the possibility of a 2-hydroxy substituent and allows the 6-phenyl moiety to be substituted with either -SO₂-N(R7)R8 or -CO-N(R9)R10 wherein R9 = H or alkyl and R10 = an optionally substituted pyridyl or phenyl radical. Accordingly, the cited WO 00/42017 reference does not teach the presently claimed substituents.

Further, the WO 97/28131 reference does not teach the possibility of a 2-hydroxy

substituent and allows the 6-phenyl moiety to be substituted with -CONR72(R73) wherein R72 and R73 = H, alkyl, cycloalkyl or cycloalkylmethyl. Accordingly, the cited WO 97/28131 reference does not teach the presently claimed substituents.

Yet further, the WO 2004/018431 reference does not teach the possibility of a 2-hydroxy substituent and allows the 6-phenyl moiety to be, among other things, -CO-NH-(NH)-NH₂. Accordingly, the cited WO 2004/018431 reference does not teach the presently claimed substituents.

The WO 02/06238 reference does not teach the possibility of a 2-hydroxy substituent and requires the 6-phenyl moiety to be substituted by at least a 3-7C-cycloalkyl or 3-7C-cycloalkylmethyl. Accordingly, the cited WO 02/06238 reference does not teach the presently claimed substituents.

The cited WO 2004/019945 and WO 2005/077906 references ultimately do not qualify as prior art against the present application. The '945 and '906 publications only qualify as prior art under 35 U.S.C. §102(e). Since the present application and the '945 publication were, at the date the presently claimed subject matter was made, subject to an obligation of assignment to the same entity, the '945 publication is disqualified under 35 U.S.C. §103(c). Similarly, since the present application and the '906 publication were, at the date the presently claimed subject matter was made, subject to an obligation of assignment to the same entity, the '906 publication is disqualified under 35 U.S.C. §103(c). See MPEP §706.02(I)(1)

The WO 99/05111 reference does not teach a hydroxyl substituent at R4 and further requires an optionally substituted tetrazol-5-yl radical as a substituent on the 6-

phenyl ring. The cited WO 02/05616 reference also does not teach a hydroxyl substituent at R4. Further, the cited WO 02/05616 reference does not teach the presently claimed substituents on the 6-phenyl ring.

Therefore, the cited art of record does not meet the minimum requirements for establishing a *prima facie* case of obviousness since it does not teach each and every element of the presently pending claims as required by *In re Wilson*.

Accordingly, applicant respectfully requests that the Examiner reconsider the cited art in view of the presently pending claims and allow the presently pending claims to proceed to grant.

III. Rejection of claims 1-12 and 14 under doctrine of obviousness-type double patenting

The Official Action states that claims 1-12 and 14 are rejected or are provisionally rejected under the doctrine of obviousness type double patenting over the following US Patents or US applications:

US 7,329,676

US 6,121,279

US 6,127,378

US 6,191,138

US 6,410,551

US 6,476,025

USSN 11/581,478

USSN 10/589,082 (also US 2007/0167482)

USSN 10/524,820 (now US 7,329,676, cited above)

USSN 12/000,710 (also US 2008/0319067).

USSN 11/590,803

USSN 10/591,472

USSN 11/795,981

USSN 11/885,423

Applicant respectfully traverses this rejection and respectfully points out to the Examiner that each of the rejected (or provisionally rejected) claims has been canceled without prejudice or disclaimer, rendering the basis of this rejection moot to these now canceled claims. However, applicant has introduced new independent claim 20 and new claims 21-25 which depend either directly or indirectly from new claim 20 – all of which are not an obvious, unlawful extension of patent scope of the claims of the cited documents above.

In this regard, presently pending independent claim 20 is directed to twenty-five specific compounds, their salts, their enantiomers and the salts of their enantiomers. Applicant respectfully submits that the cited references do not claim these specific compounds or obvious variations of these compounds. Further, the Examiner has not pointed to any teaching contained in the references that would cause the skilled artisan to modify the claims of any of the cited documents to arrive at the presently pending claims. Short of such a teaching contained in the references, the Examiner has failed to

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demonstrate a *prima facie* case of obviousness-type double patenting over the claims of the cited references.

Accordingly, applicant respectfully requests that the Examiner reconsider the cited art in view of the presently pending claims and allow the presently pending claims to proceed to grant.

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CONCLUSION

Based upon the above remarks and amendment, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider her positions taken in the previous Office Action in view of the presently pending claims, withdraw all rejections and provisional rejections and allow all pending claims in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited. The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

In the event this paper is not timely filed, applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,
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